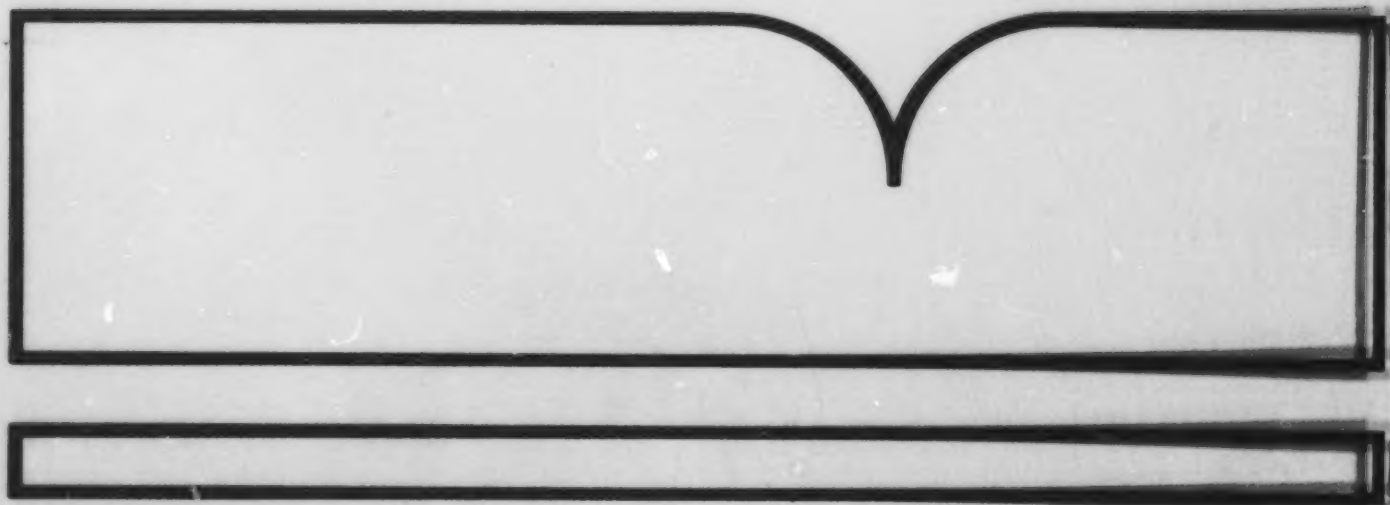


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Guidance for the Reregistration of
Pesticide Products Containing
Nitrpyrin as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING AS THE ACTIVE INGREDIENT

NITRAPYRIN
(069203)

CASE NUMBER 213

CAS 1929-82-4

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

June 1985

1.2

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of a product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption A. Single Active Ingredient Products* B. Multiple Active Ingredient Products	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document. These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, <u>will</u> be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.
* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered. NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.	

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This Registration Standard describes the regulatory position of the Environmental Protection Agency ("the Agency") on nitrapyrin based on an evaluation of the one manufacturing-use product (MP) with nitrapyrin as the sole active ingredient and the registered nitrapyrin uses. Future requests for registrations of substantially similar products containing nitrapyrin as the sole active ingredient will be covered by this Standard. After briefly describing the chemical and its uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling considerations and tolerance reassessment.

B. Description of Chemical

Nitrapyrin is the common name for 2-chloro-6-(trichloromethyl) pyridine as recognized by the American National Standards Institute. The trade name is N-Serve. The Chemical Abstract Service Registry Number (CAS) is 1929-82-4 and the Agency's Chemical Code Number is 069203.

Nitrapyrin is a white crystalline solid with a mildly sweet odor. The melting point is 62-63°C. The solubility of nitrapyrin at 20°C is 198 grams (g)/100 g in acetone and 185 g/100 g in methylene chloride; and at 22°C is 30 g/100 g in ethanol, 54-67 g/100 g in anhydrous ammonia, and 0.004 g/100 g in water. The vapor pressure is 2.8×10^{-3} mm Hg at 23°C.

Nitrapyrin is a bacteriostat used to delay the nitrification of ammoniacal and urea nitrogen fertilizer in the soil by controlling the nitrification process through selective activity against the *Nitrosomonas* bacteria. Nitrapyrin is registered for use on corn, cotton, rice, sorghum, strawberries and wheat. Registered products are a 90% active ingredient (ai) technical manufacturing-use product, a 2 pound (lb) ai per gallon emulsifiable concentrate and a 2 lb ai per gallon soluble concentrate. Nitrapyrin is soil-injected or incorporated during or immediately following application at rates ranging from 0.25 to 1.0 pound ai per acre.

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on nitrapyrin, the Agency has determined the following:

1. The existing data base is insufficient to fully assess the toxicology, residue chemistry, environmental fate, or ecological effects of nitrapyrin.

Rationale: Major data gaps exist for this chemical. Previous toxicity testing had been conducted using the major metabolite 6-chloropicolinic acid and for many studies, previous testing was found, upon reevaluation, to be supplementary (not tested in accordance with current Agency testing guidelines) or invalid. A summary of conclusions that can be reached at this time follows:

- a. Nitrapyrin has been tentatively classified in Toxicity Category III on the basis of acute oral and dermal toxicity studies. Subchronic feeding studies indicate a no-observed effect level (NOEL) of 600 parts per million (ppm) in the dog and a NOEL of 300 ppm in the rat.
- b. Chronic feeding studies were previously conducted on the metabolite 6-chloropicolinic acid (6-CPA) which was initially identified as the residue of concern since metabolism studies in plants and animals using C^{14} tagged nitrapyrin parent compound resulted in the production of 6-CPA. Subsequent testing showed nitrapyrin per se to be part of the residue on some crops. For this reason, and since parent nitrapyrin is metabolized to 6-CPA in both animals and plants, testing of the technical grade active ingredient (TGAI) will demonstrate the toxic effects of both the parent and metabolite(s), as well as impurities in the TGAI. Therefore, toxicity testing is required using nitrapyrin TGAI as the test substance.
- c. Reevaluation of a chronic feeding/oncogenicity study in the rat using 6-CPA indicated that significant compound related microscopic changes (biliary hyperplasia) occurred in female rat livers at all tested dose levels. The lowest dose tested (LDT) was 30 ppm. Testing conducted at 100, 300, and 1000 ppm dose levels indicated increased frequency and/or severity of lesions with dose. No changes were observed in the controls or treated males. Although these data are inadequate (insufficient number of animals tested, incomplete reporting of necropsy data, and incomplete clinical pathology) for assessment of oncogenic potential or establishment of a chronic NOEL, they are useful as a basis for determining a provisional acceptable daily intake (PADI) for nitrapyrin. The previously established nitrapyrin (6-CPA) NOEL, acceptable daily intake (ADI), and maximum permissible intake (MPI) will, therefore, have to be revised. (Refer to Section G. Tolerance Reassessment.)

- d. The plant and animal metabolism of nitrapyrin are not adequately understood. Due to large amounts (up to 85%) of unextractable or unidentified extractable material in plants, and depending on the results of the requested plant metabolism data, the analytical methodology may need to be revised. Animal metabolism studies testing nitrapyrin per se and its 6-CPA metabolite are required. Storage stability data, and additional, more geographically representative residue data are required for most commodities. (Refer to Section G. Tolerance Reassessment for a listing of established tolerances for nitrapyrin and 6-chloropicolinic acid.)
- e. Preliminary data indicate that hydrolysis of nitrapyrin is rapid (half-life of < 2-8 days), the rate increasing with temperature (25-45°C). It is not affected by pH (3.2-8.4); however, it degrades more rapidly in the light than in the dark. In aerobic soil, nitrapyrin has a half-life of 4-30 days, and in anaerobic soil, it has a half-life of < 3 days. In the field under flooded rice culture conditions, nitrapyrin degrades with a half-life of 7-35 days. It accumulates in the edible and visceral tissues of bluegill sunfish with maximum bioconcentration factors of 33x and 60x, respectively. The residues depurate rapidly.

Data from the following studies are required to fully assess the environmental fate and transport of and the potential exposure to nitrapyrin: hydrolysis; photodegradation in water; aerobic aquatic metabolism; leaching and adsorption/desorption; terrestrial and aquatic field dissipation; and accumulation in rotational and irrigated crops.

- f. The application of nitrapyrin as a liquid should pose no hazard to birds because it is incorporated into the soil immediately after application and acute toxicity studies show it to be practically nontoxic. Based on estimated environmental concentration (EEC) of 0.1 ppm in water (due to runoff), the hazard to aquatic organisms is expected to be minimal. Avian dietary and acute freshwater fish toxicity data are required to fully assess the effects of nitrapyrin on wildlife and aquatic organisms.

2. While available residue chemistry and toxicology data are insufficient to allow a tolerance reassessment, the Agency concludes that no changes in existing tolerances are indicated at this time. However, no new tolerances will be established until all major data requirements have been satisfied.

Rationale: There is no basis on which to change existing tolerances because available toxicology data have been used to determine that current tolerances utilize 45.6% of the provisional acceptable daily intake (PADI). Due to data gaps an acceptable daily intake (ADI) cannot be calculated at this time. Therefore, no new tolerances will be granted until data are submitted and reviewed and existing tolerances are reassessed. (Refer to Section G. Tolerance Reassessment.)

The rationale provided in #1 and #2 also supports position #3.

3. None of the risk criteria set forth in Title 40 Code of Federal Regulations (CFR) §162.11 have been met or exceeded by nitrapyrin.

4. The use of nitrapyrin in rice may impact on endangered or threatened species. Additional data are needed before the Agency can initiate formal consultation with the Office of Endangered Species (OES), USFWS.

Rationale: Although nitrapyrin use in rice is estimated to be negligible (use analysis indicates that 90-100% of nitrapyrin produced between 1981 and 1983 was used in corn), nitrapyrin residues at concentrations of 0.4 ppm (in floodwater) may result from this use. This level may impact on endangered or threatened species, such as the Fat Pocketbook Pearly Mussel, which is a bottom dweller. As a bottom feeder this species would be exposed to nitrapyrin in the water as well as that adsorbed to sediments. Because the available aquatic invertebrate toxicity data are not appropriate in assessing hazard to bivalves, marine mollusc shell deposition data are required. As soon as these data are received and evaluated the Agency will determine whether formal consultation with OES is necessary.

In the meantime the Agency is requiring a revised environmental precautionary statement on the labels of all manufacturing-use products. This statement places certain restrictions on discharge of effluent containing nitrapyrin. (Refer to Section F. 2 below.)

5. No unique human hazard precautionary statements, protective clothing requirements, or reentry intervals are required.

Rationale: Acute oral and dermal studies indicate that nitrapyrin has a relatively low toxicity (Toxicity Category III) and there is no basis to require unique precautionary statements or protective clothing requirements. Also, since nitrapyrin is soil-injected or incorporated during or immediately after application, reentry intervals are not required.

6. Current labeling restrictions for end-use products will be maintained.

Rationale: Present label restrictions prohibit rotation of non-labeled crops to treated areas within one year of application and prohibit the use of irrigation water from treated rice fields for irrigation of non-labeled crops. These restrictions will be maintained until such time as data which allow a determination of the nature and amount of residue uptake in rotational crops and crops expected to be irrigated with water from a field treated with nitrapyrin are received and reviewed. In addition, the present label statement limiting use on strawberries to California will be maintained. Expansion of this use to other areas will require appropriate supporting data.

7. The environmental chemistry studies (hydrolysis, photo-degradation, mobility, metabolism and dissipation) are being required in the minimum times necessary to conduct the tests and will be evaluated on an expedited basis when received to assess the potential for nitrapyrin to contaminate ground water.

Rationale: Nitrapyrin per se has not been previously identified as a potential ground water contaminant and in monitoring studies conducted to date nitrapyrin residues have not been found in ground water. However, one study using the 6-CPA metabolite indicated a moderate potential for 6-CPA to leach in loam soil. Therefore, these studies are being requested on an expedited basis and will be evaluated as they are received. The Agency will then determine if the registration(s) of nitrapyrin will be affected.

8. Manufacturing-use pesticide products containing nitrapyrin as a sole active ingredient may be registered for sale, distribution and reformulation, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to permit new nitrapyrin registrations.

Rationale: In the absence of evidence indicating that the use of a pesticide would cause unreasonable adverse effects on the environment, the Agency can register or allow the continued registration of a product for which necessary data is missing or inadequate. Issuance of this Standard provides a mechanism for identifying such data needs. Data submitted to fill these gaps will be reviewed and evaluated. The Agency will then determine if they will affect registration(s) of nitrapyrin.

D. Criteria for Registration Under This Standard

To be subject to this Standard, manufacturing-use products must meet the following conditions:

1. Contain nitrapyrin as the sole active ingredient and,
2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section E of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it, including committing to fill data gaps on a schedule agreed to by both this Agency and the applicant. All applicants for registration under this Standard must follow the instructions contained in this Standard and complete and submit the appropriate forms within the time specified.

E. Acceptable Ranges and Limits

1. Product Composition Standard. To be covered under this Standard manufacturing-use products (MP) must contain nitrapyrin as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits. The Agency will consider registration of technical grade products and manufacturing-use products containing nitrapyrin with a Toxicity Category III for all acute studies.

3. Use Patterns. To be registered under this Standard, manufacturing-use products containing nitrapyrin may be labeled for formulation into end-use products for the commodities listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

a. Terrestrial, non-domestic, food use on: corn, cotton, sorghum, strawberries and wheat.

b. Aquatic food use on rice.

F. Required Labeling

All manufacturing-use and end-use nitrapyrin products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains information on label requirements.

In addition to the above, the following information must appear on the labeling:

1. Use Pattern Statements

All manufacturing-use product labeling must list specific, currently registered sites on which the product is intended for use after manufacture into an end-use product or the manufacturing-use product will be considered for manufacture into end-use products for all registered use sites. Specific sites are listed in Section E.3, Use Patterns.

2. Precautionary Statements

Statements Applicable to Manufacturing-Use Products

The following environmental precautionary statement must appear on all MP labels:

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Statements Applicable to End-Use Products

The following chemical-specific restrictive statements must appear on all EP labels:

- a. "Crops listed on this label may be rotated in less than one year from the last application. All other crops are not to be rotated in less than one year from the last application."
- b. "Irrigation water from treated rice fields can be used only on the following crops: corn, cotton, sorghum, and wheat."
- c. "Based on available residue data, use of N-Serve on strawberries is restricted to California."

The required label statements listed in this Standard must appear on the labels of all MPs and EPs released for shipment within one year of issuance of this document. All labeling requirements must appear on all products in channels of trade within two years of issuance of this document. After review of data to be submitted under this Standard, the Agency may impose additional label requirements.

G. Tolerance Reassessment

U.S. tolerances for residues of nitrapyrin [2-chloro-6-(trichloromethyl) pyridine] and its metabolite, 6-chloropicolinic acid, in or on raw agricultural commodities are as follows [40 CFR §180.350]:

<u>Commodities</u>	<u>Tolerance (ppm)</u>
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Corn, fodder	1.0
Corn, forage	1.0
Corn, grain	0.1
Corn, fresh	0.1
Cottonseed	1.0
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Rice, grain	0.2
Rice, straw	2.0
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05
Sorghum, fodder	0.5
Sorghum, forage	0.1
Sorghum, grain	0.1
Strawberries	0.2
Wheat, forage	0.5
Wheat, grain	0.1
Wheat, straw	0.5

No Codex Alimentarius Commission Maximum Residue Limits or Mexican tolerances have been established for residues of nitrapyrin. A Canadian tolerance of 0.1 ppm has been established for residues of nitrapyrin per se in or on corn, however, it is not known if the specific residues determined are consistent with the U.S. tolerance.

The theoretical maximum residue contribution (TMRC) to the human diet as a result of the existing tolerances is 0.0411 mg/day/1.5 kg of the diet.

A tolerance reassessment cannot be made at this time because of the major data gaps associated with the residue chemistry and toxicology of nitrapyrin.

Since reevaluation of the oncogenicity study in the rat using 6-CPA found it to be invalid, the previously established nitrapyrin (6-CPA) NOEL of 300 ppm, the ADI, and the MPI values, which were based on this study, are considered negated. A provisional ADI (PADI) and MPI (PMPI) have been established utilizing currently available feeding/oncogenicity studies.

The ADI for man is usually determined on the basis of a no-observed effect level (NOEL) which has been established for chronic toxicity in rats or dogs. In the absence of a valid chronic feeding study, a PADI can be determined based on a NOEL generated from an acceptable subchronic feeding study, providing that an appropriate margin of safety is used. A safety factor of 100 is normally applied when the PADI is based on a chronic test, whereas a safety factor of 2000 is used when basing the PADI on a subchronic test. Chronic studies, even those classified as supplementary, may be considered in determining a PADI.

Taking into consideration the length of the chronic rat feeding/oncogenicity study, the compound tested (i.e., 6-CPA), and the fact that significant histopathological effects were observed at the lowest dose tested (30 ppm), the Agency has selected a more appropriate safety factor of 1000 to be used in determining a PADI.

Based upon all the above considerations, the PADI has been calculated to be 0.0015 mg/kg/day. The PMPI is 0.09 mg/day. Currently, the total TMRC stands at 0.0411 mg/day/1.5 kg diet. The current percent of the PADI utilized is therefore 45.6%.

Tolerances have been proposed for residues of nitrapyrin and its metabolite, 6-CPA, in or on the crop group cereal grains; lettuce; potatoes; soybeans and soybean forage and hay. Since the existing toxicology and residue chemistry data base for nitrapyrin is incomplete, the Agency has decided that no new tolerances or exemptions will be established until all major toxicology and residue chemistry data requirements listed in Table A have been satisfied.

EPA Index to Pesticide Chemicals

NITRAPYRIN*

TYPE PESTICIDE: Nitrogen Stabilizer

FORMULATIONS:

Tech (90%)

EC (2 lb a.i./gal)

SC/L (2 lb a.i./gal)

GENERAL WARNINGS AND LIMITATIONS: Nitrapyrin nitrogen stabilizer is corrosive to aluminum components which may affect the operation of pumping, mixing and application equipment. To minimize corrosion of equipment and for maximum effectiveness do not store liquid nitrogen solutions containing the emulsifiable concentrate formulation. Do not store anhydrous ammonia containing the soluble concentrate/liquid formulation for any longer than 3 weeks. Use the emulsifiable concentrate formulation within 72 hours of mixing and rinse equipment with water after each use. Nitrapyrin must be injected or incorporated into the soil with fertilizer at a minimum depth of 2 to 4 inches during or immediately after application. The soluble concentrate/liquid formulation is an oil-soluble product that may be used with anhydrous ammonia, dry ammonium and urea fertilizers. Do not use the soluble concentrate/liquid formulation with fertilizers containing nitrate, such as ammonium nitrate, potassium nitrate or calcium nitrate. Do not mix seeds with dry fertilizers impregnated with the soluble concentrate/liquid formulation. The emulsifiable concentrate formulation may be used with aqua ammonia, other liquid ammonical or urea nitrogen fertilizer compositions or liquid animal wastes. Combustible: do not use hot mix fertilizers. Do not contaminate water, food or feed by storage or disposal. Only those crops listed on the label may be rotated in less than 1 year from the last application.

Livestock Tolerances:**

0.05 ppm (meat, fat, and meat byproducts of cattle)

0.05 ppm (meat, fat, and meat byproducts of goats)

0.05 ppm (meat, fat, and meat byproducts of hogs)

0.05 ppm (meat, fat, and meat byproducts of horses)

0.05 ppm (meat, fat, and meat byproducts of poultry)

0.05 ppm (meat, fat, and meat byproducts of sheep)

**Tolerance established for combined residue of nitrapyrin and its metabolite, 6-chloropicolinic acid.

Replacement Crop Tolerances: None.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: None.

PHYTOTOXICITY TO CROPS: None.

MODE OF ACTION: Used to delay the nitrification of ammoniacal and urea nitrogen fertilizer compositions in the soil by controlling the nitrification process.

*N-Serve

2-chloro-6-(trichloromethyl)pyridine

EPA Index to Pesticide Chemicals

NITRAPYRIN

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

AGRICULTURAL CROPS

General Warnings and Limitations: Incorporate nitrapyrin to a depth of 2 to 4 inches. Make only 1 application per year.

Corn

1.0 ppm (forage and fodder)
0.1 ppm (grain)
0.1 ppm (fresh corn (including sweet (kernel plus
cob with husk removed)))

0.25-0.5
(2 lb/gal EC)
(2 lb/gal SC/L)

Preplant or at planting, row or band application.
Use higher rates with all fall applications and
most spring applications.

0.5-1
(2 lb/gal EC)

Preplant or at planting broadcast application.
Use the higher rate when fall applications are
made on spring planted crops. May be tank mixed
with EPTC, butylate, atrazine, alachlor, cyana-
zine, metolachlor, or combinations of butylate
with atrazine or cyanazine.

0.5-1
(2 lb/gal SC/L)

Preplant or at planting broadcast application.
Use the higher rate when fall applications are
made for spring planted crops.

0.5-1
(2 lb/gal EC)

Preplant application with liquid animal wastes in
the fall or spring. Use the higher rates for all
fall applications with animal wastes.

0.25-0.5
(2 lb/gal EC)
(2 lb/gal SC/L)

Postplant row or band application. Use up to 30
days after planting.

Cotton

1.0 ppm (cottonseed)

0.25-0.5
(2 lb/gal EC)

Preplant or at planting band application. Use
higher rate when applied in the fall to spring
planted cotton.

0.25-0.5
(2 lb/gal EC)

Preplant or at planting broadcast application.
Use higher rate when applied in the fall to spring
planted cotton. May be tank mixed with triflura-
lin, profluralin or pendimethalin.

NITRAPYRIN

Site, Dosage
and Formulation
(lb a.i./A)Tolerance, Use, LimitationsCotton (continued)0.25-0.3
(2 lb/gal SC/L)Preplant or at planting broadcast application.
Use higher rate when applied in the fall to spring
planted cotton.0.25
(2 lb/gal EC)
(2 lb/gal SC/L)Postplant row or band application. Use up to 45
days after planting.Rice0.2 ppm (grain)
2.0 ppm (straw)0.5-1
(2 lb/gal EC)
(2 lb/gal SC/L)Preplant or at planting application. Rice fields
should be flooded within 30 days of seeding and
the flood should be maintained throughout the
growing season. Irrigation water from treated
rice fields can only be used on corn, cotton, sor-
ghum and wheat. May be tank mixed with molinate.Sorghum0.5 ppm (fodder)
0.1 ppm (grain and forage)0.25-0.5
(2 lb/gal EC)
(2 lb/gal SC/L)Preplant or at planting band or row application.
Use higher rate with fall and most spring appli-
cations.0.5-1
(2 lb/gal EC)Preplant or at planting broadcast application.
Use the higher rate when fall applications are
made for spring planted crops. May be tank mixed
with atrazine or cyanazine.0.5-1
(2 lb/gal SC/L)Preplant or at planting broadcast application.
Use the higher rate when fall applications are
made for spring planted crops.0.5-1
(2 lb/gal EC)Preplant application with liquid animal wastes in
the fall or spring. Use the higher rates for all
fall applications with animal wastes.Strawberries

0.2 ppm (strawberries)

0.5
(2 lb/gal EC, SCL)Use limited to California. Preplant application.
Plant strawberries as soon as practical there-
after.

EPA Index to Pesticide Chemicals

NITRAPYRIN

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Wheat

0.1 ppm (grain)
0.5 ppm (forage and fodder)

0.25-0.5
(2 lb/gal EC)
(2 lb/gal SC/L)

Preplant or at planting band or row application.
Use the higher rate with all fall and most spring
applications.

0.5-1
(2 lb/gal EC)
(2 lb/gal SC/L)

Preplant or at planting broadcast application.
Use the higher rates when fall applications are
made for spring planted crops.

0.5-1
(2 lb/gal EC)

Preplant application with liquid animal wastes in
spring or fall. Use the higher rate for all fall
applications with animal wastes.

EPA Index to Pesticide Chemicals

NITRAPYRIN

Listing of Registered Pesticide Products by Formulation

90% technical concentrate

nitrapyrin (069203)

000464-00434

2 lb/gal emulsifiable concentrate

nitrapyrin (069203)

000464-00432

2 lb/gal soluble concentrate

nitrapyrin (069203)

000464-00433

State Label Registrations

AZ Reg. No.

000464-06843

000464-06843

CA Reg. No.

000464-06842

000464-06844

EPA Index to Pesticide Chemicals

NITRAPYRIN

Appendix A

Listing of Common Chemical Names Used on the Entry

<u>Chemical Code</u>	<u>Common Name (source)</u>	<u>EPA Acceptable Common/Chemical Name</u>
041401	EPTC	S-ethyl-N,N-dipropylthiocarbamate
041402	Molinate	S-ethyl hexahydro-1H-azepine-1-carbo- thioate
041403	Butylate	S-ethyl diisobutylthiocarbamate

EPA Index to Pesticide Chemicals

NITRAPYRIN

Appendix B

Listing of Registration Numbers By Site

Corn

000464-00432	000464-00433	000464-06842	000464-06843
000464-06844	000464-06845		

Cotton

000464-00432	000464-00433	000464-06842	000464-06843
000464-06844	000464-06845		

Rice

000464-00432	000464-00433		
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Sorghum

000464-00432	000464-00433	000464-06842	000464-06843
000464-06844	000464-06845		

Strawberries

000464-00432	000464-00433		
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Wheat

000464-00432	000464-00433	000464-06842	000464-06843
000464-06844	000464-06845		

EPA Index to Pesticide Chemicals

NITRAPYRIN

COMMENTS

Listing of Registered 24-C Pesticide Products

<u>State Number</u>	<u>Federal Registration Number</u>
AR79002100	000464-00432
AR79002400	000464-00433
AR82000300	000464-00432
AR82000400	000464-00433
KY79000600	000464-00433
LA79002100	000464-00433

Listing of Registered 24-C Pesticide Products By Site

<u>Corn</u>	
KY79000600	000464-00433

<u>Cotton</u>	
AR79002100	000464-00432
AR79002400	000464-00433
LA79002100	000464-00433

<u>Rice</u>	
AR82000300	000464-00432
AR82000400	000464-00433

The Index to Pesticide Chemicals

NITRAPYRIN

COMMENTS

Pesticide Products Containing Nitrapyrin

<u>Reg. No.</u>	<u>Active Ingredient</u>	<u>Formulation</u>	<u>Product Name</u>	<u>Manufacturer</u>
464-432	Nitrapyrin	24.3% EC	N-Serve 24E	Dow Chemical Co.
464-433	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co.
464-434	Nitrapyrin	90% Tech	N-Serve TG	Dow Chemical Co.
464-6842	Nitrapyrin	24.3% EC	N-Serve 24E	Dow Chemical Co. (CA only)
464-6843	Nitrapyrin	24.3% EC	N-Serve 24E	Dow Chemical Co. (AZ only)
464-6844	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (CA only)
464-6845	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (AZ only)
AR79002100	Nitrapyrin	24.3% EC	N-Serve 24E	Dow Chemical Co. (AZ only)
AR79002400	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (AZ only)
AR82000300	Nitrapyrin	24.3% EC	N-Serve 24E	Dow Chemical Co. (AZ only)
AR82000400	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (AZ only)
KY79000600	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (KY only)
LA79002100	Nitrapyrin	24.7% SC/L	N-Serve 24	Dow Chemical Co. (LA only)

COMMENTS

Listing of Product, Common and Chemical Names

Chem Code	Product Name	Common Name	Chemical Name	Manufacturer
080803		Atrazine	2-chloro-4-ethylamino-6-isopropylamine-1,3,5-triazine	Shell Chemical Co.
100101	Bladex	Cyanazine	2((4-chloro-6-(ethylamino)-s-triazine-2-yl)amino)-2-methylpropionitrile	Shell Chemical Co.
041401	Eradreane EPTC + R-25788		S-ethyl-N,N-dipropylthiocarbamate plus n,n-diallyl-1,1-dichloroacetamide (inert safener)	Stauffer Chemical Co
090501	Lasso	Alachlor	2-chloro-2',6'-diethyl-N-(methoxymethyl)-acetanilide	Monsanto Co.
108801	Dual	Metolachlor	2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide	CIBA-Giegy Corp.
041402	Ordram	Molinate	S-ethyl hexahydro-1H-azepine-1-carbothioate	Stauffer Chemical Co.
108501	Prowl	Pendimethalin	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamide	American Cyanamid Co.
041405	Sutant + R-25788	Butylate + R-25788	S-ethyl diisobutylthiocarbamate plus N,N-diallyl-1,1-dichloroacetamide (inert safener)	Stauffer Chemical Co.
106601	Tolban	Profluralin	N-(cyclopropylmethyl)-s,s,a-trifluoro-2,6-dinitro-N-propyl-p-toluidine	CIBA-Geigy Corp.
036101	Treflan	Trifluralin	s,s,a-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine	Elanco Products Co.
069203	N-Serve	Nitropyrin	2-chloro-6-(trichloromethyl)pyridine	Dow Chemical Co.

REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data^{1/} Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines ^{2/} or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD)). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

^{1/} Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

^{2/} The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)* /

* / FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

Guideline Citation and Name of Test	Test Substance/	Guidelines Status/	Are Data Required	Footnote Number	Data Must Be Submitted Within Timeframes Listed Below/
Yes	No				
<u>\$158.120 Product Chemistry</u>					
<u>Product Identity and Composition:</u>					
61-1 - Product Identity and Disclosure of Ingredients	TGAI	R	☒		6 Months
61-2 - Description of Beginning Mate- rials and Manufacturing Process	TGAI	R	☒		6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	☒		6 Months
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis of Product Samples	TGAI	CR	☒		12 Months
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R	☒		6 Months
63-3 - Physical State	TGAI	R	☒		6 Months
63-4 - Odor	TGAI	R	☒		6 Months
63-5 - Melting Point	TGAI	R	☒		6 Months
63-6 - Boiling Point	N/A3/	R	☒		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒		6 Months

Guideline Citation and Name of Test	Test Substance ^{1/}	Guidelines Status ^{4/}	Are Data Required		Footnote Number	Data Must Be Submitted Within Timeframes Listed Below ^{2/}
			Yes	No		
\$158.120 Product Chemistry (continued)						
63-8 - Solubility	TGAI or PAI	R	☒	☐		6 Months
63-9 - Vapor Pressure	PAI	R	☒	☐		6 Months
63-10 - Dissociation Constant	PAI	R	☒	☐		6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	R	☒	☐		6 Months
63-12 - pH	TGAI	R	☒	☐		6 Months
63-13 - Stability	TGAI	R	☒	☐		6 Months
Other Requirement:						
64-1 - Submittal of samples	N/A	CR	☐	☒		

^{1/} Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

^{2/} Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
 ° 6 Month Due Date is December 31, 1985.
 ° 12 Month Due Date is June 30, 1986.

^{3/} Not required because the 90% technical is a solid at room temperature.

^{4/} R = Required; CR = Conditionally required

Must Additional Data
Be Submitted Under
FIPRA § 3(c)(2)(B)?
Timeframe for Data
Submission^{2/}

Does EPA Have Data
To Satisfy This
Requirement? (Yes,
No, or Partially)

Composition^{1/}

Data Requirement

Bibliographic
Citation

\$158.125 Residue Chemistry

171-4 - Nature of Residue (Metabolism)

- Plants

PAIRA

Partially

Yes^{3/} 24 Months

00110311 ✓
00116907 ✓
00037878 ✓
00037873 ✓
00088727 ✓
00037876 ✓
00037870 ✓
00037872 ✓

- Livestock

PAIRA and plant
metabolites

Partially

Yes^{4/} 18 Months

00037875 ✓
00038480 ✓
00116901 ✓
00116902 ✓
00116919 ✓

171-4 - Residue Analytical Method

- Plant residues

TOAI and plant
metabolites

Partially

Yes^{5/} 24 Months

00088737 ✓
00040049 ✓
00110314 ✓
00039625 ✓
00037886 ✓
00037887 ✓
00052964 ✓
00040046 ✓
00109457 ✓
00037881 ✓
00039620 ✓
00052343 ✓
00039624 ✓

Must Additional Data
Be Submitted Under
FIFRA § 3(c)(2)(B)?
Timeframes For Data
Submission^{2/}

Does EPA Have Data
To Satisfy This
Requirement? (Yes,
No, or Partially)

Composition^{1/}

Data Requirement

Bibliographic
Citation

\$158.125 Residue Chemistry
(continued)

- Animal residues

TGAI and metabolites

Partially

00037886 ✓
00037885 ✓
00037888 ✓
00037882 ✓

Yes^{5/} 18 Months

171-4 - Storage Stability Data

PAI

Partially

00040049 ✓
00040054 ✓
00076728 ✓
00052343 ✓
00040056 ✓
00040057 ✓
00039619 ✓
00110311 ✓
GS0213001 ✓
GS0213002 ✓

Yes^{6/} 24 Months

171-4 - Magnitude of the Residue-
(Residue Studies for Each
Food Use)

- Crop Group # 1 - Cereal Grains

o Crop # 1 Corn (Grain and Sweet)

- Crop field trials

TEP

Partially

00110318 ✓
00040048 ✓
00040050 ✓

Yes^{7a/} 24 Months

- Processed Food/Feed^{7b/}

EP

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{2/}	

\$158.125 Residue Chemistry
(continued)

° Crop #2 - Rice (Grain)					
— Crop Field Trials	TEP	Yes	00052963 ✓	No ^{8/}	24 Months
— Processed Food/Feed	EP	Yes	00052963 ✓	No ^{8/}	24 Months
° Crop #3 - Sorghum (Grain)					
— Crop Field Trials	TEP	Partially	00039619 ✓	Yes ^{9a/}	24 Months
— Processed Food/Feed ^{9b/}	EP				
° Crop #4 - Wheat (Grain)					
— Crop Field Trials	TEP	Partially	00037881 ✓	Yes ^{10a,c/}	24 Months
— Processed Food/Feed ^{10b/}	EP		00039620 ✓		

- Crop Group #2 - Forage, Fodder and Straw of Cereal Grains

° Crop #1 - Corn Forage and Fodder					
— Crop Field Trials	TEP	Partially	00040046 ✓ 00040048 ✓ 00040050 ✓ 00110318 ✓	Yes ^{11/}	24 Months
° Crop #2 - Rice Straw					
— Crop Field Trials	TEP	Yes	00052963 ✓	No ^{12/}	24 Months

Must Additional Data
Be Submitted Under
PIFRA § 3(c)(2)(B)?
Timeframes For Data
Submission^{2/}

Does EPA Have Data
To Satisfy This
Requirement? (Yes,
No, or Partially)

Bibliographic
Citation

Composition^{1/}

Data Requirement

\$158.125 Residue Chemistry
(continued)

◦ Crop #3 - Sorghum Forage and Fodder				Yes ^{13a/} 24 Months
-- Crop Field Trials	TEP	Partially	00039619 ✓ 00040046 ✓	
-- Processed Food/Feed	EP	No		Yes ^{13b/} 24 Months
◦ Crop #4 - Wheat Forage and Straw				
-- Crop Field Trials	TEP	Partially	00037881 ✓ 00040046 ✓ 00039620 ✓	Yes ^{14/} 24 Months
- Crop Group #3 - Small Fruits and Berries				
◦ Crop - Strawberries				
-- Crop Field Trials	TEP	Partially	00052341 ✓ 00052343 ✓	Yes ^{15/} 24 Months
- Miscellaneous Crops				
◦ Crop - Cottonseed				
-- Crop Field Trials	TEP	Partially	00088737 ✓ 00110314 ✓	Yes ^{16a/} 24 Months
-- Processed Food/Feed	EP	Partially	00040053 ✓	^{16b/} 24 Months

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{2/}
§158.125 Residue Chemistry (continued)				
- Meat/Poultry	TGAI or plant metabolites	Partially ^{17a/}	00040054 00040055 00040056 00040057	No ^{17b/} 18 Months

- 1/ Composition: TGAI = Technical grade of the active ingredient; FAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
- 2/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
 - o 18 Month Due Date is December 31, 1986.
 - o 24 Month Due Date is June 30, 1987.
- 3/ Additional Data Required: Corn and two other representative crops such as potatoes and soybeans must be grown to maturity in soil treated at-planting with ring-labeled [¹⁴C] nitrapyrin. Definitive techniques such as GC/MS must be used to characterize residues following exhaustive extraction procedures which include hydrolytic steps. A wide variety of potential metabolites must be sought such as CO₂, oxidative intermediates, and dechlorinated and decarboxylated residues as well as related pyridine impurities in the technical.
- 4/ Additional Data Required: Poultry and ruminants must be fed both ring-labeled (¹⁴C) nitrapyrin and ring-labeled (¹⁴C) 6-chloropicolinic acid (6-CPA) metabolite in separate tests for at least 3 days. The distribution and nature of residues must be determined within 24 hours of dosing cessation in at least muscle, liver, kidney, and fat. Additionally, milk and eggs must be collected twice daily for analysis. If ruminant and/or poultry metabolism differ from that in rats (not adequately defined to our knowledge), then we will also require swine metabolism studies.
- 5/ Additional Data Required: One or more methods must be developed which determine 6-CPA, nitrapyrin per se, and any additional residues of concern based on the requested plant and animal metabolism studies. Representative crops bearing "weathered" residues and animal tissues must be extracted using one or more solvent systems and then sequentially hydrolyzed using acid, base, and enzymatic systems (glycosidases, lipases, proteases). Recoveries of all residues of concern must be determined after each step. It is preferred that [¹⁴C] nitrapyrin be used for treatments (this could be incorporated into the plant and animal metabolism studies). Samples must contain detectable residues at or above the tolerance level.

158.125 Residue Chemistry (continued)

- 6/ Additional Data Required: Storage stability of nitrapyrin per se in or on corn grain, forage, fodder, fresh corn and in animal tissues, milk, and eggs. Storage stability of any additional residues of concern in or on representative plant and animal commodities if metabolism studies reveal new metabolites of concern. To validate the currently available data on wheat grain and straw, stability data are required reflecting storage at room temperature for the duration used in the residue tests.
- 7/ Additional Data Required: a) Separate tests reflecting at-plant applications of the 2 lb/gal EC or SC/L at 1 lb ai/A and postplant applications at 0.5 lb ai/A (made 30 days postplant) must be conducted on sweet corn in FL, IL, MN, NY, OR or WA, and WI and must be conducted on field corn in representative states such as IA, IN, MN, and NE. Residues of the parent compound and 6-CPA, free and tissue-bound, must be determined as well as any new residues of concern as determined from the requested plant metabolism studies. b) If residues are detected, then processing studies must be conducted to determine residues in milling products, crude and refined oil, and cannery waste.
- 8/ No residue data on rice required at this time, including processed products. However data may be required in the future pending the outcome of requested plant metabolism, storage stability, and methodology studies.
- 9/ Additional Data Required: a) Sorghum grain must be analyzed for residues of nitrapyrin, 6-CPA (bound and free), and any additional residues of concern. Sorghum grown in KS, NE, and TX must be treated at-plant with the 2 lb/gal EC or SC/L formulation at 1 lb ai/A (broadcast and soil-incorporated). b) If residues occur in grain, then a fractionation study would be required (if not translated from wheat).
- 10/ Additional Data Required: a) Wheat grown in CA, IL, KS, ND, TX and WA must be treated with the 2 lb/gal EC or SC/L formulation of nitrapyrin at-plant (broadcast and soil-incorporated). Mature grain must be harvested and analyzed for residues of nitrapyrin per se, 6-CPA (free and tissue-bound), and any additional residues of concern as identified in the requested plant metabolism data. b) If residues of concern are detected in grain, a fractionation study will be required. c) To validate the currently available data, storage stability data reflecting room temperature storage of grain for appropriate duration must be submitted as well.
- 11/ Additional Data Required: Separate tests reflecting at-plant application of the 2 lb/gal EC or SC/L at 1 lb ai/A and postplant applications at 0.5 lb ai/A (made 30 days postplant) must be conducted in IA, MN, NE, PA, and WI. Residues of nitrapyrin and 6-CPA (free and tissue-bound) in or on corn forage and fodder as well as any additional residues of concern, identified in the requested plant metabolism studies are to be determined.
- 12/ No residue data are required on rice straw at this time. However data may be required in the future depending upon the outcome of the requested plant metabolism, storage stability, and methodology studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

\$158.125 Residue Chemistry (continued)

- 13/ Additional Data Required: a) Sorghum forage, fodder, and hay must be analyzed for residues of nitrapyrin per se, 6-CPA (bound and free), and any additional residues of concern. Sorghum grown in GA, KS, and SD must be treated at-plant with the 2 lb/gal EC or SC/L formulation at 1 lb ai/A (broadcast and soil-incorporated). b) A processing study should be conducted to determine the above residues in sorghum syrup.
- 14/ Additional Data Required: Wheat grown in CA, IL, KS, ND, TX, and WA must be treated with the 2 lb/gal EC or SC/L formulation of nitrapyrin at-plant (broadcast and soil-incorporated). Forage and straw must be harvested and analyzed for residues of nitrapyrin per se, 6-CPA (free and tissue-bound), and any additional residues of concern as identified in the requested plant metabolism data. To validate the currently available data, storage stability data reflecting room storage of grain for appropriate duration must be submitted as well.
- 15/ Additional Data Required: Studies must be conducted in strawberry growing areas of Monterey and Ventura counties in CA. The 2 lb/gal EC or SC/L must be soil-incorporated at 0.5 lb ai/A within a few days preplant. Nitrapyrin, 6-CPA, and any additional residues of concern must be determined.
- 16/ Additional Data Required: a) In separate tests conducted in AZ, CA, MS, and TX, at-plant and postplant applications of the 2 lb/gal EC or SC/L must be made at 0.5 and 0.25 lb ai/A, respectively. A single annual, soil-incorporated treatment must be made at each site. Mature cottonseed and forage must be analyzed for residues of nitrapyrin per se, 6-CPA (free and tissue-bound), and any additional residues of concern identified in the requested plant metabolism studies. b) Additional data may be required on processed products of cottonseed pending results of the requested residue data, plant metabolism data, storage stability data, and revised analytical methods, if necessary.
- 17/ a) The number of milk samples (00040056) and the intervals between swine and poultry dosage cessation and slaughter must be specified. b) No additional live-stock feeding studies are required at this time. However, additional data may be required in the future depending on the outcome of the requested plant and animal metabolism studies, storage stability data, and revised methodology (if necessary). Note that nitrapyrin per se, and perhaps metabolites other than 6-CPA, may need to be administered and determined in the future.

TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition/	Use Pattern?	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ³ /
<u>\$158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	A, C	No		Yes 9 Months
Photodegradation					
161-2 - In Water	TGAI or PAIRA	A, C	No		Yes 9 Months
161-3 - On Soil	TGAI or PAIRA	N/A	N/A		No ⁴ /
161-4 - In Air	TGAI or PAIRA	N/A	N/A		No ⁵ /
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic Soil	TGAI or PAIRA	A	Yes	00117010	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00117998	No ⁶ /
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	Yes	00117998	No
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No		Yes 27 Months
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A, C	Partially	00079381	Yes ⁷ / 12 Months
163-2 - Volatility (Lab)	TEP	N/A	N/A	001102918/	No ⁵ /
163-3 - Volatility (Field)	TEP	N/A	N/A		No ⁵ /

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TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>\$158.130 Environmental Fate (continued)</u>					
<u>DISSIPATION STUDIES-FIELD:</u>					
164-1 - Soil	TEP	A	No		Yes 27 Months
164-2 - Aquatic (Sediment)	TEP	C	No		Yes 27 Months
164-3 - Forestry	TEP	N/A	N/A		No ^{9/}
164-4 - Combination and Tank Mixes		N/A	N/A		No ^{10/}
164-5 - Soil, Long-term	TEP	A	N/A		No ^{11/}
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes ¹² 39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Yes ^{12/} 50 Months
165-3 - Irrigated Crops	TEP	A	No		Yes ^{13/} 39 Months
165-4 - In Fish	TGAI or PAIRA	A,C	Yes	00101635	No
165-5 - In Aquatic Non-Target Organisms	TEP	N/A	N/A		No ^{14/}
Subpart K Re-entry		N/A	N/A		No ^{5/}

^{1/} Composition: TGAI - Technical grade of the active ingredient; PAIRA - Pure active ingredient, radiolabelled, TEP = typical end-use product.

\$158.13 Environmental Fate (continued)

- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; N = Domestic Outdoor; I = Indoor.
- 3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
 - o 9 Month Due Date is March 31, 1986.
 - o 12 Month Due Date is June 30, 1986.
 - o 27 Month Due Date is September 30, 1987.
 - o 39 Month Due Date is September 30, 1988.
 - o 50 Month Due Date is August 31, 1989.
- 4/ No data are required since nitrapyrin is soil injected or incorporated upon application.
- 5/ Exposure is not expected to be significant since all currently registered uses of nitrapyrin require soil injection or incorporation during or immediately after application; and since nitrapyrin has been tentatively classified in Toxicity Category III on the basis of acute oral and dermal toxicity studies.
- 6/ Acceptable data for anaerobic aquatic metabolism 162-3 will also satisfy the requirement for anaerobic soil metabolism 162-2.
- 7/ Data on the adsorption of 6-chloropicolinic acid (a degradate of nitrapyrin) to a loam soil are acceptable. All other data are required.
- 8/ This study would be acceptable, however, it is not required to support current use patterns of nitrapyrin.
- 9/ No data are required since nitrapyrin is not registered for forestry use.
- 10/ Data requirements for combination products and tank mixes are not being imposed for this Standard.
- 11/ No data are required since results of a valid aerobic soil metabolism study demonstrate that greater than 50% of residues dissipate prior to recommended subsequent application.
- 12/ Data are required to determine: a) the nature and amount of pesticide residue uptake in rotational crops, b) a realistic crop rotation restriction (time from application to a time when crops can be rotated), and c) to determine if tolerances are needed in rotational crops.
- 13/ Data are required to determine: a) residue uptake and levels in crops which are expected to be irrigated with water from a rice field treated with nitrapyrin, b) a realistic label restriction to prevent illegal residues in irrigated crops, and/or c) whether tolerances may be needed in the irrigated crop.
- 14/ No data are required for terrestrial or aquatic food crop use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>\$158.135 Toxicology</u>					
<u>ACUTE TESTING:</u>					
81-1 - Acute Oral Toxicity	TGAI	A	Yes	00037519	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	No		Yes 9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	No		Yes 9 Months
81-4 - Primary Eye Irritation- Rabbit	TGAI	A	No		Yes 9 Months
81-5 - Primary Dermal Irritation- Rabbit	TGAI	A	Yes	00037522	No
81-6 - Dermal Sensitization	TGAI	A	No		Yes 9 Months
81-7 - Acute Delayed Neurotoxicity - Hen			N/A ^{4/}		No
<u>SUBCHRONIC TESTING:</u>					
82-1 - 90-Day Feeding: - Rodent (Rat), and Non-rodent (Dog)	TGAI	A	No		No ^{5/}
82-2 - 21-Day Dermal	TGAI	A	No		No ^{6/}
82-3 - 90-Day Dermal			N/A ^{7/}		No
			N/A ^{8/}		No

TABLE
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>\$158.135 Toxicology (continued)</u>					
82-4 - 90-Day Inhalation -			N/A ^{9/}		No
82-5 - 90-Day Neurotoxicity - Hen/Mammal			N/A ^{10/}		No
<u>CHRONIC TESTING:</u>					
83-1 - Chronic Toxicity - 2 species: - Rodent (Rat-2 yr.) and - Non-rodent (Dog-1 yr.)	TGAI TGAI	A A	No No		Yes 50 Months Yes 50 Months
83-2 - Oncogenicity - 2 species: - Rat (preferred) - 2 yrs., and - Mouse (preferred) - 18 month	TGAI TGAI	A A	No No		Yes 50 Months Yes 50 Months
83-3 - Teratogenicity - 2 species: - Rat - Rabbit (preferred)	TGAI TGAI	A A	No No		Yes 15 Months Yes 15 Months
83-4 - Reproduction - 2-generation	TGAI	A	No		Yes ^{11/} 39 Months
<u>MUTAGENICITY TESTING</u>					
84-2 - Gene Mutation Ames	TGAI	A	No		Yes 9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A	No		Yes 12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>§158.135 Toxicology (continued)</u>					
84-2 - Other Genotoxic Effects					
DNA Damage & Repair: Unscheduled DNA Synthesis	TGAI	A	Yes	00109456	No
<u>SPECIAL TESTING:</u>					
85-1 - General Metabolism - Rat (perferred)	TGAI	A	No		Yes 24 Months

1/ Composition: Material to be tested is technical grade unless otherwise specified in footnotes (TGAI: technical grade of the active ingredient).
The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

2/ Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
 ◦ 9 Month Due Date is March 31, 1986.
 ◦ 12 Month Due Date is June 30, 1986.
 ◦ 15 Month Due Date is September 30, 1986.
 ◦ 24 Month Due Date is June 30, 1987.
 ◦ 39 Month Due Date is September 30, 1988.
 ◦ 50 Month Due Date is August 31, 1989.

4/ Not applicable since nitrapyrin is not an organophosphate.

5/ Not required since 2-year rat chronic feeding study is required.

6/ Not required since 1-year dog chronic feeding study is required.



§158.135 Toxicology (continued)

- 7/ Not applicable since use of nitrapyrin is not likely to result in repeated human skin contact.
- 8/ Not applicable since use of nitrapyrin does not involve purposeful application to the human skin.
- 9/ Not applicable since nitrapyrin is not expected to result in repeated inhalation exposure at a concentration likely to be toxic.
- 10/ Required only when acute delayed neurotoxicity test or acute oral, dermal, or inhalation studies show neuropathy or neurotoxicity. Nitrapyrin is not known to be closely related structurally to a compound which can induce such effects.
- 11/ A 2-generation reproduction study is required using one species employed in a teratology study.

T/
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition	Use Patterns	Does EPA have DATA To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>§158.140 Reentry Protection</u>					
132-1 - Foliar Dissipation	N/A	N/A	N/A		No ^{1/}
132-1 - Soil Dissipation	N/A	N/A	N/A		No ^{1/}
133-1 - Dermal Exposure	N/A	N/A	N/A		No ^{1/}
133-4 - Inhalation Exposure	N/A	N/A	N/A		No ^{1/}

^{1/} Not applicable. Data to support establishment of reentry protection standards are not required because the Agency has determined, based on use patterns (soil injection or incorporation during or immediately after application) for nitrapyrin, that the criteria in part 158.140 are not met.

TABLE 1
GENERIC DATA REQUIREMENTS FOR DDT/DDE/DDEP

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>\$158.145 Wildlife and Aquatic Organisms</u>					
<u>AVIAN AND MAMMAL TESTING</u>					
70-1 Special Test	Degradation Product	A,C	Yes ^{6/}	00117016*	No
71-1 Acute Avian Oral Toxicity	TGAI	A,C	Yes	00110296*	No
71-2 Avian Subacute Dietary Toxicity	TGAI	A,C	Partially	00116899**	Yes 9 Months
71-3 Wild Mammal Toxicity	TGAI	A,C	No		No
71-4 Avian Reproduction	TGAI	A,C	No		No
71-5 Simulated and Actual Field Testing - Mammals and Birds	TEP	A,C	No		No
<u>AQUATIC ORGANISM TESTING</u>					
72-1 Freshwater Fish Toxicity Warmwater Coldwater	TGAI TGAI TEP	A,C A,C C	Partially Partially No	00110297** 00110297**	Yes 9 Months Yes 9 Months Reserved ^{4/}
72-2 Acute Freshwater Invertebrates	TGAI TEP	A,C C	Partially No	00110298	Yes 9 Months Reserved ^{4/}

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TABLE A
GENERIC DATA REQUIREMENTS FOR NITRAPYRIN

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>\$158.145 Wildlife and Aquatic Organisms (continued)</u>					
72-3 Acute Toxicity to Estuarine and Marine Organisms					
- Mollusc	TGAI	A, C	No		Yes ^{4/} 5, 7/ 12 Months
72-4 Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A, C	No		Reserved ^{4/}
72-5 Fish Life-Cycle	TGAI	A, C	No		Reserved ^{4/}
72-6 Aquatic Organism Accumulation	TGAI	A, C	No		Reserved ^{4/}
72-7 Simulated or Actual Field Testing - Aquatic Organisms	TEP	A, C	No		Reserved ^{4/}

^{1/} Composition: TGAI - Technical Grade of the Active Ingredient; TEP - Typical End-use Product.

^{2/} The use patterns are coded as follows: A, Terrestrial Food Crop; B, Terrestrial Non-Food Crop; C, Aquatic Food Crop; D, Aquatic Non-Food Crop; E, Greenhouse Food Crop; F, Greenhouse Non-Food Crop; G, Forestry; H, Domestic Outdoor; I, Indoor.

^{3/} Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
 ° 9 Month Due Date is March 31, 1986.
 ° 12 Month Due Date is June 30, 1986.

§158.145 Wildlife and Aquatic Organisms (continued)

- 4/ Studies may be required pending environmental fate data and additional data on the TGA1.
- 5/ Required for rice use and such crops as cotton and sorghum where 300,000+ acres are grown in coastal counties.
- 6/ Currently, there is no requirement for degradation products.
- 7/ Only oyster shell deposition test required.
- * Study fulfills data requirement on its own.
- ** Study must be cited along with additional data to fulfill data requirement.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B—Product-Specific Data Requirements for Manufacturing Use Products—lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NITRAPYRIN

Guideline Citation and Name of Test	Test Substance ^{1/}	Guidelines Status ^{4/}	Are Data Required Yes ☐ No ☐	Footnote Number	Data Must Be Submitted Within Timeframes Listed Below ^{2/}
<u>\$158.120 Product Chemistry</u>					
<u>Product Identity and Composition:</u>					
61-1 - Product Identity and Disclosure of Ingredients	MP	R	☒ ☐		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	☒ ☐		6 Months
61-3 - Discussion of Formation of Impurities	MP	R	☒ ☐		6 Months
<u>Analysis and Certification of Product Ingredients:</u>					
62-1 - Preliminary Analysis of Product Samples	MP	CR	☒ ☐		12 Months
62-2 - Certification of Ingredient Limits	MP	R	☒ ☐		12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	R	☒ ☐		12 Months
<u>Physical and Chemical Characteristics:</u>					
63-2 - Color	MP	R	☒ ☐		6 Months
63-3 - Physical State	MP	R	☒ ☐		6 Months
63-4 - Odor	MP	R	☒ ☐		6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☒ ☐		6 Months

Guideline Citation and Name of Test	Test Substance ^{1/}	Guidelines Status ^{4/}	Are Data Required		Footnote Number	Data Must Be Submitted Within Timeframes Listed Below ^{2/}
			Yes	No		
<u>158.120 Product Chemistry (continued)</u>						
63-12 - pH	MP	CR	☒	☐		6 Months
63-14 - Oxidizing or Reducing Action	MP	CR	☒	☐		6 Months
63-15 - Flammability	N/A ^{3/}	CR	☐	☒		
63-16 - Explodability	MP	R	☒	☐		6 Months
63-17 - Storage Stability	MP	R	☒	☐		15 Months
63-18 - Viscosity	N/A ^{3/}	CR	☐	☒		
63-19 - Miscibility	N/A ^{3/}	CR	☐	☒		
<u>Other Requirements:</u>						
64-1 - Submittal of samples	N/A	CR	☐	☒		

^{1/} Composition: MP = Manufacturing-use product.

^{2/} Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

- ° 6 Month Due Date is December 31, 1985.
- ° 12 Month Due Date is June 30, 1986.
- ° 15 Month Due Date is September 30, 1986.

^{3/} Not required because the product is solid at room temperature.

^{4/} R = Required; CR = Conditionally required

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. **PRODUCT NAME** - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. **NET CONTENTS** - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word Minimum Type Size All Capitals</u>	<u>"Keep Out of Reach of Children" Minimum Type Size</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(11)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(1)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(1)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(11)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(11)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(1)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(11)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

1. The flame extension is zero inches;

11. There is no flashback; and

111. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d)
requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv))

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing Nitrapyrin as an active ingredient:

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

- a. Confidential Statement of Formula, EPA Form 8570-4.
- b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).
- c. Two copies of any required product-specific data.
- d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.
- e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing Nitrapyrin in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing Nitrapyrin alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 (enclosed) for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing Nitrapyrin either as the sole active ingredient or in combination with other active ingredients:

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

Richard F. Mountfort
Product Manager 23
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-1830

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Appendix II-1

Guide to Use of This Bibliography

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

Appendix II-1 (continued)

- a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.
- b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Nitrapyrin Standard

Appendix II-2

<u>MRID</u>	<u>CITATION</u>
00037519	Norris, J.M.; Plomer, E.; Bourne, J.E.; et al. (1971) Acute Toxicological Properties of Dowco 163. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092163-J)
00037522	Wolf, M.A. (1963) Results of Human Skin Irritation and Skin Sensitization Studies on N-serve Nutrient Conserver 2-Chloro-6-(trichloromethyl) pyridine. (Unpublished study including M-312, received Apr 29, 1972 under 2F1265; prepared in cooperation with Hill Top Research Institute, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092163-M)
00037870	Redemann, C.T. (1962) Residues from 2-Chloro-6-(trichloromethyl)-14C-pyridine in Lettuce and in Soil: GS 510. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-D)
00037872	Redemann, C.T. (1962) The Fate of 2-Chloro-6-(trichloromethyl)-14C-pyridine Applied to Cotton under Greenhouse Conditions: GS 516. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-F)
00037873	Redemann, C.T. (1961) Metabolism of 2-Chloro-6-trichloromethylpyridine by the Corn Plant: GS-465. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-G)
00037875	Redemann, C.T. (1961) Metabolism of 2-Chloro-6-trichloromethyl-14C-pyridine in the Dog: GS-459. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-I)
00037876	Redemann, C.T. (1962) Residues from 2-Chloro-6-(trichloromethyl)-14C-pyridine in Oats: GS 520. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-J)
00037878	Meikle, R.W.; Williams, E.A.; Redemann, C.T. (1966) Residues from 2-Chloro-6-trichloromethyl-14C-pyridine in Cotton Seed Grown in the Field: GS 755. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-L)
00037881	Jensen, D.J.; Miller, P.W. (1973) Studies To Determine Possible Bound Residues of 6-Chloropicolinic acid (6-CPA) in Wheat: GH-C 655. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-P)

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<u>MRID</u>	<u>CITATION</u>
00037882	Miller, P.W. (1973) A Comparison of Retention Times of 6-Chloropicolinic acid and Some Commonly Used Herbicides by Gas Chromatography: GH-C 649. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-Q)
00037885	Jensen, D.J. (1970) Determination of Residues of 6-Chloropicolinic acid in Milk by Gas Chromatography. Method ACR 70.1 dated Jan 27, 1970. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-U)
00037886	Swann, R.L.; Ramsey, J.C., ed. (1972) Determination of Residues of 6-Chloropicolinic acid in Plant and Animal Tissues. Method ACR 71.8R dated Mar 20, 1972. (Unpublished study received Jun 6, 1973 under 2F1265; prepared in cooperation with International Research and Development Corp., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-V)
00037887	Ramsey, J.C., ed. (1971) Determination of Residues of 6-Chloropicolinic acid in Corn, Sorghum, Potatoes, and Sugar Beets by Gas Chromatography. Method ACR 71.9 dated Jun 24, 1971. (Unpublished study received Jun 6, 1973 under 2F1265; prepared in cooperation with WARF Institute, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-W)
00037888	Ramsey, J.C.; Jensen, D.J. (1971) Gas Chromatographic Method for the Determination of 6-Chloropicolinic acid Residues in Eggs. Method ACR 71.15 dated Aug 23, 1971. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-X)
00038480	Ramsey, J.C.; Rose, J.Q.; Braun, W.H.; et al. (1973) Fate of 6-Chloropicolinic acid following Oral Administration in Rats. (Unpublished study received Jun 6, 1973 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092164-O)
00039619	Ramsey, J.C.; Jensen, D.J.; Getzendaner, M.E.; et al. (1971) Residues of 6-Chloropicolinic acid in Sorghum and Sugar Beets. (Unpublished study including GH-C 469 and GH-C 471, received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-E)
00039620	Ramsey, J.C.; Jensen, D.J.; Getzendaner, M.E.; et al. (1971) Wheat. Summary of studies 092162-C, 092162-M and 092162-P. (Unpublished study including GH-C 468, received Apr 29, 1972 under 2F1265; prepared in cooperation with Univ. of Idaho, Dept. of Plant Science and Farmland Industries, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-F)

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<u>MRID</u>	<u>CITATION</u>
00039624	Swann, R.L.; Ramsey, J.C., ed. (1971) Determination of Residues of 6-Chloropicolinic acid in Plant and Animal Tissues. Method ACR 71.8 dated Jun 7, 1971. (Unpublished study received Apr 29, 1972 under 2F1265; prepared in cooperation with International Research and Development Corp., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-M)
00039625	Ramsey, J.C., ed. (1971) Gas Chromatographic Method for the Determination of 6-Chloropicolinic acid Residues in Wheat. Method ACR 71.7 dated Jun 7, 1971. (Unpublished study received Apr 29, 1972 under 2F1265; prepared in cooperation with WARF Institute, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-P)
00040046	Ramsey, J.C. (1971) Residue Studies of 2-Chloro-6-(trichloromethyl) pyridine in Corn Stover, Sorghum Stover, and Wheat Forage from Fields Treated with N-serve (R) 24 Nitrogen Stabilizer. Includes method dated Dec 20, 1971. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-Q)
00040048	Kutschinski, A.H.; Turner, G.O.; Watson, A.J.; et al. (1964) Determination of 6-Chloropicolinic acid Residues in Silage Corn, Sweet Corn Kernels and Field Corn Grain Grown on Soil Treated with N-serve. (Unpublished study received Apr 29, 1972 under 2F1265; prepared in cooperation with Purdue Univ., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-S)
00040049	Dow Chemical Company (1964) Gas Chromatographic Method for the Determination of 6-Chloropicolinic acid Residues in Silage Corn, Milk-Stage Kernels, and Field Corn Grain. Method ACR 64.1 dated Feb 19, 1964. (Unpublished study received Apr 29, 1972 under 2F1265; CDL:092162-T)
00040050	Ramsey, J.C.; Jenson, D.J.; Getzendaner, M.E.; et al. (1971) Residue Studies of Corn Grain and Stover from Fields Treated with N-serve (R) Nitrogen Stabilizer. (Unpublished study received Apr 29, 1972 under 2F1265; prepared in cooperation with Ridgeway Technical College, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-U)
00040053	Jensen, D.J.; Duan, R.J.; Turner, G.O. (1970) A Residue Study of 6-Chloropicolinic acid in Cottonseed Milling Fractions: GH-C 407(R). (Unpublished study received Apr 29, 1972 under 2F1265; prepared in cooperation with WARF Institute, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-X)

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<u>MRID</u>	<u>CITATION</u>
00040054	Gentry, W.M.; Bucek, O.C.; Swart, R.W. (1971) Determination of 6-Chloropicolinic acid in Tissues of Beef Calves Given 6-Chloropicolinic acid in the Feed. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-Y)
00040055	Ramsey, J.C.; Jensen, D.J.; Getzendaner, M.E. (1971) A Residue Study in Swine Tissues from Swine Fed 6-Chloropicolinic acid. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-Z)
00040056	Jensen, D.J. (1971) Assay for residues in milk and cream from cows fed 6-Chloropicolinic acid. Journal of Agricultural and Food Chemistry 19(5):897-899. (Also in unpublished submission received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-AA)
00040057	Ramsey, J.C.; Jensen, D.J.; Getzendaner, M.E. (1971) A Residue Study in Chicken Tissues and Eggs from Chickens Fed 6-Chloropicolinic acid. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092162-AB)
00052341	Dinoff, T.M.; Iwata, Y.; Gunther, F.A.; et al. (1979) The Results of Tests on the Amount of Nitrapyrin and 6-Chloropicolinic acid Residues Remaining in or on Strawberries, Including a Description of the Analytical Method Used. (Unpublished study received Jun 24, 1980 under 464-432; prepared in cooperation with Univ. of California--Riverside, South Coast Field Station, Dept. of Entomology, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099484-B)
00052343	Iwata, Y.; Dinoff, T.M.; Bailey, J.B.; et al. (1979) Determination of Nitrapyrin and 6-Chloropicolinic acid in Strawberry Fruit and Soil Resulting from a Preplant Soil Application of N-Serve (R). (Unpublished study received Jun 24, 1980 under 464-432; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099484-D)
00052963	Dow Chemical U.S.A. (1980) Residue Studies on Rice. (Compilation; unpublished study received Sep 4, 1980 under 464-432; CDL:099615-L)
00052964	Jensen, D.J.; Barringer, V.D.; Bjerke, E.L.; et al. (1978) Determination of 6-Chloropicolinic acid in Corn, Rice and Cottonseed. Method ACR 77.16 dated Feb 17, 1978. (Unpublished study received Sep 4, 1980 under 464-432; prepared in cooperation with WARF Institute, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099615-M)

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<u>MRID</u>	<u>CITATION</u>
00076728	Getzdaner, M.E.; Daun, R.J. (1968) A Residue Study of 6-Chloropicolinic Acid in or on Cottonseed from the Use of N-serve (TM) 24 Nitrogen Stabilizer. (Unpublished study received Jun 2, 1981 under 464-432; prepared in cooperation with Wisconsin Alumni Research Foundation, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:245291-A)
00079381	Hamaker, J.W. (1967) The Sorption of 6-Chloropicolinic Acid by Soils. (Unpublished study received Jul 30, 1981 under 464-432; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:245682-E)
00088727	Redemann, C.T. (1961) Metabolism of 2-Chloro-6-trichloromethyl-C14-pyridine by the Tomato Plant. (Unpublished study received Mar 2, 1963 under PP0408; submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:090440-J)
00088737	Dow Chemical Company (1963) Studies of Residues from Various Chemicals in Cottonseed. (Compilation; unpublished study received Mar 2, 1963 under PP0408; CDL:090440-AA)
00101635	Bidlack, H. (1982) Determination of the Bioconcentration Factor for Nitrapyrin 2-Chloro-6-(trichloromethyl)pyridine in Bluegill Sunfish during Continuous Aqueous Exposure: GH-C 1531. (Unpublished study received May 19, 1982 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:247521-A)
00109456	Mendrala, A.; Schumann, A. (1982) N-Serve TG ...: Evaluation of N-Serve TG in the Rat Hepatocyte Unscheduled DNA Synthesis Assay. (Unpublished study received Jul 26, 1982 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:071017-D)
00109457	Dow Chemical U.S.A. (1982) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method: 6-Chloropicolinic Acid and Nitrapyrin. (Compilation; unpublished study received Jul 26, 1982 under 464-432; CDL: 071017-E)
00110294	McCall, P.; Swann, R. (1978) Nitrapyrin volatility from soil. Down to Earth 34(3):21-27. (Also in unpublished submission received Jun 2, 1978 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:234113-B)
00110296	Fink, R.; Beavers, J.; Grimes, J.; et al. (1978) Final Report: Acute Oral LD50—Mallard Duck: Nitrapyrin: Project No. 103-185. (Unpublished study received Jun 21, 1979 under 464-432; prepared by Wildlife International Ltd., submitted by Dow Chemical U.S.A., Midland, MI; CDL:238687-A)

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00110297	McCarty, W. (1978) Toxicity of Nitrapyrin to Rainbow Trout and Bluegill: ES-248. (Unpublished study received Jun 21, 1979 under 464-430; submitted by Dow Chemical U.S.A., Midland, MI; CDL:238687-B)
00110298	McCarty, W. (1977) Toxicity of Nitrapyrin to Daphnids: Laboratory Report Code ES-182. (Unpublished study received Jun 21, 1979 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:238687-C)
00110311	Dow Chemical U.S.A. (1977) The Results of Tests on the Amount of Residues Remaining Including a Description of the Analytical Methods. (Compilation; unpublished study received Jun 17, 1977 under 464-433; CDL:096193-A)
00110314	Dow Chemical U.S.A. (1979) Residues of 6-Chloropicolinic Acid in or on Cottonseed. (Compilation; unpublished study received Jun 21, 1979 under 464-432; CDL:098329-A)
00110318	Jensen, D.; Bjerke, E. (1978) A Residue Study: 6-Chloropicolinic Acid in Corn from Fields Receiving Sidedress Treatments of N-Serve Nitrogen Stabilizer: GH-C 1108. (Unpublished study received Jul 12, 1978 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:097381-A)
00116899	Stevenson, G.; Palm, B.; Lapham, K. (1968) A Game Bird Toxicology Study--Acute Dietary Feeding of N-serve and 6-Chloropicolinic Acid to Japanese Quail: GH-A 375. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical Co., Indianapolis, IN; CDL:092161-I)
00116901	Redemann, C.; Williams, E.; Clark, H.; et al. (1966) The excretion of N-(6-chloropicolinoyl)-glycine by the dog fed 2-chloro-6-(trichloromethyl) pyridine. Agricultural and Food Chemistry 14 (5):530-532. (Also in unpublished submission received Apr 29, 1972 under 2F1265; submitted by Dow Chemical Co., Indianapolis, IN; CDL:092161-L)
00116902	Redemann, C.; Clark, H. (1967) Fate of 2-chloro-6-(trichloromethyl) pyridine in the rat. Agricultural and Food Chemistry 15(6): 1127-1128. (Also in unpublished submission received Apr 29, 1972 under 2F1265; submitted by Dow Chemical Co., Indianapolis, IN; CDL:092161-M)
00116907	Meikle, R.; Austin, S.; Turner, G. (1968) Crop Uptake and Soil Residues from 6-Chloropicolinic Acid Applied to Field Soil: GS 914. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical Co., Indianapolis, IN; CDL:092161-S)

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<u>MRID</u>	<u>CITATION</u>
00116919	Youngson, C. (1969) A Study of the Accumulation of 6-Chloropicolinic Acid by Aquatic Food Chain Organisms: GS 985. (Unpublished study received Apr 29, 1972 under 2F1265; submitted by Dow Chemical Co., Indianapolis, IN; CDL:092161-AF)
00117010	Regoli, A.; Kurihara, N.; Laskowski, D. (1974) Soil Degradation of ¹⁴ C-Nitrapyrin, the Active Ingredient of N-serve Nitrogen Stabilizer. (Unpublished study received Mar 1, 1974 under 464-322; submitted by Dow Chemical U.S.A., Midland, MI; CDL:092166-A)
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00117998	Oliver, G.; Swann, R.; Hertel, J. (1982) Anaerobic Soil Degradation of Nitrapyrin: GH-C 1585. (Unpublished study received Nov 9, 1982 under 464-432; submitted by Dow Chemical U.S.A., Midland, MI; CDL:248798-A)
GS0213001	Bjerke, E.L.; Woods, W.J.; and Kutschinski, A.H. (1982) A residue study of 6-chloropicolinic acid and nitrapyrin in soybeans. (Unpublished study received 7/26/82 under PP2F2733; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:071017).
GS0213002	IR-4 at Rutgers (1982) Section D of Petition 2E2757. (Unpublished study received 9/14/82; CDL:071092).

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

DUCT NAME

LICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

th respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced guidance Document, I am responding in the following manner:

- ☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

- ☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(iii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

- ☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

- ☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

- ☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

**CERTIFICATION OF ATTEMPT TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA**

qualify, certify ALL four items)

I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM

EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM

DATE OF OFFER

However, none of those firm(s) accepted my offer.

I request that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

PRINTED NAME

SIGNATURE

DATE

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No. _____ Guidance Document for _____

Date _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submit- ting Data (At- tached)	
\$158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk- density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Appendix III-1 (continued)

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submit- ting Data (At- tached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric break- down voltage				
\$158.135					
TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitiza- tion				

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

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(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label—(i) General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a

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wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers—(A) Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known";

(C) "Pollution approved";

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for . . ." "Distributed by . . ." or "Sold by . . ." to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No.," The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

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allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement—(1) General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.*

(i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

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(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may

appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC ₅₀	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD ₅₀	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects.....	Corrosive: corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects.....	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher

Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

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placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

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Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	8	6
Above 5 to 10	10	8
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the

hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the

pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 120° F may cause bursting.
Flash point above 20° F and not over 90° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 120° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 90° F	Flammable. Keep away from heat and open flame.
Above 90° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use—(1) General requirements—(i) Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on

printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use—(A)* Detailed directions for use may be omitted from labeling of pesticides which are intended

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for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product, for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

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(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type

of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—*

(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . ." etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. al/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT		LABEL PREFERRED	COMMENTS
			REQUIRED			
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None		Same as above	
9A	Restricted block	All restricted products	Top center of front panel		Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use			
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use		Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use		Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use.
10D	Directions for use	All products	None		None	May be in metric as well as U.S. units

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (If DOMESTIC ANIMALS) CAUTION ENVIRONMENTAL HAZARDS PHYSICAL OR CHEMICAL HAZARDS	PRODUCT NAME ACTIVE INGREDIENT _____ % INERT INGREDIENTS _____ % TOTAL _____ 100.00 % THIS PRODUCT CONTAINS _____ LBS OF _____ PER GALLON	KEEP OUT OF REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT IF SWALLOWED _____ IF INHALED _____ IF ON SKIN _____ IF IN EYES _____ SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
DIRECTIONS FOR USE REENTRY STATEMENT (If Applicable) STORAGE AND DISPOSAL STORAGE _____ DISPOSAL _____	WARRANTY STATEMENT	NET CONTENTS

PHYSICAL-CHEMICAL HAZARDS

<u>Criteria</u>	<u>Required Label Statement</u>
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. <u>ALL OTHER PRESSURIZED CONTAINERS</u>	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30.	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

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(continued)

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."
2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

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(continued)

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

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(continued)

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused ¹ , dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

¹/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

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(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewhere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramidate (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)phthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichloroethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

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(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone	Formaldehyde
Acetonitrile	Formic acid
Acetophenone	Isobutyl alcohol
Acrylic acid	Meleic anhydride
Aniline	Methyl alcohol (methanol)
Benzene	Methyl ethyl ketone
Chlorobenzene	Methyl methacrylate
Chloroform	Naphthalene
Cyclohexane	Saccharin and salts
Cyclohexanone	Thiourea
Dichlorodifluoromethane (Freon 12 [®])	Toluene
Diethyl phthalate	1,1,1-Trichloroethane
Dimethylamine	1,1,2-Trichloroethane
Dimethyl phthalate	Trichlorofluoromethane (Freon 11 [®])
1,4-Dioxane	Vinyl chloride
Ethylene oxide	Xylene